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Transgenic blood proteins: An abundant source for next generation therapies with worldwide availability

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The use of cultured animal cells to produce complex human proteins has almost eliminated the risk of disease transmission as experienced from biotherapeutics originally derived from human blood. Prime examples of proteins having exceptionally complex structure and functions that are now available as recombinant analogues are Factor VIII and Factor IX which are used to treat hemophilia A and B, respectively. However, these are limited in supply worldwide. Notably, significant amounts of factor are needed to induce tolerization in response to adverse, titrating antibodies that occur after intravenous administration. Thus, the next goal of biotechnology is to provide non-intravenous therapies that simultaneously achieve immune tolerization with pharmacokinetically longer lasting activity. A quantum increase in abundance is needed to enable these advances which would both increase the quality of patient life and make treatment more affordable. Importantly, the US FDA and EMEA have both approved transgenic (tg) animal-derived therapies thus establishing a regulatory precedent, albeit for less complex proteins such as tg-antithrombin III in the milk of goats. Both tg-Factor VIII (tg-FVIII) and tg-Factor IX (tg-FIX) made from the milk of pigs are on the cusp of being next generation Biotherapeutics that might achieve a quantum leap in supply to counter the low bioavailability that nonintravenous therapies such as buccal delivery inherently possess. Here, we presenta review of the biochemical characterization of tg-FVIII, tg-FIX, and tg-fibrinogen as well as preclinical animal studies in mice, dogs and pigs which show promising physiologic function.

Biography

In 2003, Bill Velander became chairperson of the Department of Chemical Engineering at the University of Nebraska-Lincoln. During his tenure, Velander has emphasized the role of bioengineering by changing the Department name to Chemical and Biomolecular Engineering and adding a new field specialization in Chemical and Biomolecular Engineering to the College of Engineering Unified Ph.D. Program. Under Velander's leadership, six of nine biomolecular faculty members currently hold research grants from the National Institutes of Health (NIH). The Department is currently ranked 14 among 158 departments of chemical engineering in research expenditures according to the NSF.

Velander is the principal investigator of a $10 million, five-year NIH grant awarded to the University of Nebraska-Lincoln in September, 2005 for research on recombinant hemophilia factors. He was also the principal investigator of a $5 million grant from the US Army for the production of a fibrinogen hemostatic bandage.

Velander is an elected fellow of the American Institute of Medical & Biological Engineering. He was instrumental in the formulation of federal regulatory guidelines for human therapeutics derived from transgenic animals through his consultancy with the USFDA. He is a co-inventor of several US patents concerning the production of recombinant proteins of hemostasis.

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